K071371
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Section B – 510(K) Summary

Date Summary Was Prepared: May 11, 2007

Submitter's Information:

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NOV 19 2007

Contact:

James Welsh
VP, Regulatory Affairs
Kendall
a Division of Tyco Healthcare Group LP
Telephone: 508-261-8532
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Device Trade Name: COPA AMD Antimicrobial Wound Dressing

Device Common Name: Wound Dressing, Antimicrobial

Classification Panel: General and Plastic Surgery

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
The COPA AMD antimicrobial wound dressing is substantially equivalent to the existing COPA (Curafoam) polyurethane foam wound dressings in intended use, materials, physical characteristics, and performance characteristics. The modification attributed to the predicate device is the addition of PHMB antimicrobial agent to prevent bacterial penetration and colonization of the dressing.

Substantial equivalence is also claimed to Kerlix AMD and Excilon AMD, absorbent wound dressings which contain PHBM antimicrobial agent to prevent bacterial penetration and colonization of the dressing.

KENDALL 15 HAMPSHIRE STREET, MANSFIELD, MASSACHUSETTS 02048 • (508) 261-8000

Section B – 510(K) Summary

Device Description:
COPA AMD is a hydrophilic polyurethane foam that is impregnated with Polyhexamethylene Biguanide Hydrochloride (PHMB), an antimicrobial agent that protects the dressing from bacterial penetration and colonization.

Intended Use:

COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.

Performance Data: Performance data submitted in support of this 510k included in-vitro and animal testing.

Broad spectrum activity was demonstrated against 6 organisms including gram positive, gram negative, and fungal types. Total kill was achieved for 7 consecutive days, with a daily challenge of >6 log of each organism:

- P. aeruginosa
- E. coli
- C. albicans
- S. epidermidis
- S. aureus
- E. faecalis

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 2007

Tyco Healthcare LLP
% Mr. James Welsh
VP, Regulatory Affairs
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K071371
Trade/Device Name: COPA AMD antimicrobial wound dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 2, 2007
Received: November 7, 2007

Dear Mr. Welsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Mark N. Melkerson 11/14/07

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) number: K071371

Device Name:

COPA AMD antimicrobial wound dressing

Indications for Use:

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Prescription Use____x_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071371